

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----X
CASSAVA SCIENCES, INC.,

Plaintiff,

-against-

ADRIAN HEILBUT, et al.,

Defendants.
-----X

22-CV-9409 (GHW) (OTW)

**REPORT & RECOMMENDATION TO
THE HONORABLE GREGORY H.
WOODS**

ONA T. WANG, United States Magistrate Judge:

I. INTRODUCTION

This is a defamation and civil conspiracy case brought by Cassava Sciences, Inc. (“Cassava”) against three groups¹ of short sellers of Cassava stock, who allegedly profited from their investments by publishing (and republishing) allegedly defamatory statements about Cassava’s development of simufilam (or “PTI-125”), a drug intended to treat Alzheimer’s disease. All three groups of defendants have moved to dismiss the First Amended Complaint (“FAC”) (ECF 30). This Report and Recommendation addresses the motion to dismiss² filed by Defendants Adrian Heilbut, Jesse Brodtkin, and Enea Milioris (collectively, the “Dot.Com Defendants”) (See ECF 86).³ For the reasons below, I respectfully recommend that the Dot.Com Defendants’ motion be **GRANTED**.

¹ The three groups are (1) the “Neuroscientist Defendants,” David Bredt and Geoffrey Pitt (see ECF 74); (2) Quintessential Capital Management LLC (see ECF Nos. 77 and 78); and (3) the Dot.Com Defendants (see ECF 86).

² The briefing on the Dot.Com Defendants’ motion to dismiss is located at ECF Nos. 87, 95, and 96.

³ The FAC also names Patrick Markey, Ph.D., as one of the Dot.Com Defendants and a resident of Germany (see FAC ¶ 21-22), but the docket reflects that his summons issued on November 3, 2022 (ECF 27) and was executed on August 9, 2023 (ECF 98), and that Dr. Markey has not responded to the FAC. Dr. Markey has not entered an appearance or moved to dismiss the FAC. Indeed, it does not appear that he was ever served with the FAC. The

II. FACTUAL BACKGROUND

The Court assumes familiarity with the basic science, factual background and analysis in my prior Report and Recommendation recommending dismissal of the claims against the Neuroscientist Defendants (ECF 104, hereinafter the “Neuroscientists’ R&R”). The Dot.Com Defendants’ allegedly defamatory statements reference the Neuroscientist Defendants’ public filings, explain their concerns in simpler language, and apparently draw the same inferences as were drawn by the Neuroscientist Defendants. The FAC acknowledges that all of the Dot.Com Defendants hold Ph.D. degrees. (FAC ¶¶ 18-21). These Defendants also conducted additional inquiries, including requests under the Freedom of Information Act (FOIA) and New York’s Freedom of Information Law (FOIL), the results of which they used to further support their inferences, and apparently posted their findings on two websites called “cassavafraud.com” and “simuflimflam.com.” (FAC ¶¶ 18-22).

A. Dot.Com Defendants’ Statements

Cassava asserts that the Dot.Com Defendants made at least four allegedly defamatory statements in November and December 2021, which were published on “cassavafraud.com” and “simuflimflam.com”:

1. The November 2, 2021 Letter to the FDA (ECF 30-8, the “November 2 FDA Letter”);
2. The November 3, 2021 Presentation entitled “Cassava Sciences: A Shambolic Charade” (ECF 30-9, the “Shambolic Charade Presentation”);
3. The November 29 Report named “SavaDX_Theranos2.0.pdf” and entitled “SavaDX Exposed – A revolutionary diagnostic for Alzheimer’s Disease or a scam of scientifically illiterate investors?” (ECF 30-12, the “SavaDX Report”);⁴ and

other Dot.Com Defendants’ arguments apply equally to Dr. Markey, however, as there is no indication he engaged in different conduct, and so I will refer to the Dot.Com Defendants as a group that includes Defendant Markey.

⁴ See also FAC ¶ 149.

4. The December 10, 2021 Presentation entitled “Cassava and the Wang Lab: Seeing Through the Blind” (ECF 30-14, the “Seeing Through the Blind Presentation”).

The Dot.Com Defendants’ statements all questioned the integrity of Cassava’s and Dr. Wang’s research. I will summarize each of these in turn.

i. The November 2 FDA Letter

The Dot.Com Defendants’ first salvo was a letter to the FDA that, like the Neuroscientist Defendants’ letters to the FDA, “express[ed] grave concerns regarding Cassava Sciences as a sponsor of clinical studies using [s]imufilam to treat Alzheimer’s disease.” (ECF 30-8 at 2). The Dot.Com Defendants claim to have assessed “virtually every aspect of their program that has been made available for public scrutiny.” *Id.* Referencing publicly available documents and data, the Dot.Com Defendants claim that their analysis identified at least four areas of concern regarding Cassava’s development and testing of simufilam:

1. “fabrication of pre-clinical and clinical evidence”;
2. “inadequate and unreliable safety studies”;
3. “serious misconduct in the analysis and reporting of clinical trial data”; and
4. “improper and opaque study conduct” by Cassava and its scientists. *Id.*

The November 2 FDA Letter discussed the unlikely background of Filamin-A (“FLNA”) involvement in Alzheimer’s disease and in simufilam’s binding affinity to it, noting that the discovery of simufilam arose from Dr. Wang’s and Cassava’s predecessor’s (Pain Therapeutics) research into binding of naloxone to FLNA over the mu opioid receptor. *Id.* at 3; *see also* ECF 30-6 at 13 (containing link to retracted 2008 *PLoS One* article). Among other concerns, the Dot.Com Defendants – relying on publicly available papers co-authored by Dr. Wang, Dr. Burns and their colleagues – note that if simufilam binds with FLNA at the femtomolar, sub-picomolar levels reported in the Stage 2a trial, and crosses the blood-brain barrier at the levels reported in

Cassava's papers, then the amounts of simufilam being administered in the current clinical trials are **3 million times** too high. (ECF 30-8 at 3; *see also, e.g.*, ECF 30-13 at 5–7). Moreover, FLNA is found in other structures in the body, including in smooth muscle. *Id.* If simufilam's binding affinity is as high as Cassava represents, then given the dosages reportedly used by Cassava in its clinical trials, simufilam would bind to all of the FLNA in the body "to saturation." *Id.*

According to a paper co-authored by Dr. Burns, simufilam acts as an inhibitor of FLNA function. *Id.* If all of these findings are accurate, then "one may expect to see widespread effects on scaffolding and signaling function in tissues in which [FLNA] is abundant, which have not been reported by either pre-clinical or clinical research with [s]imufilam so far." *Id.* at 4.

The letter goes on to raise other examples of implausible results reported in the publications used by Cassava to support the action of simufilam. Like the Neuroscientist Defendants' statements, the Dot.Com Defendants draw inferences and raise questions in the November 2 FDA Letter using the data reported by Cassava and Cassava-affiliated scientists, and applying basic scientific principles and mathematical calculations. As one example, the Dot.Com Defendants "back-calculated" baseline albumin levels, "a key biomarker of blood-brain barrier [] integrity," to show that they are several orders of magnitude out of normal range. *Id.* at 7–8.

The letter also challenges "post-hoc data manipulation," or the exclusion of subjects based on reasons that were not identified in the testing protocol. *Id.* at 14. For the cognitive trials, this led to 40% (27 out of 64) of the subjects being excluded from the analysis of Stage 2b altogether. *Id.* The letter identifies other instances where unfavorable data was excluded, "to skew the data in a favorable direction." *Id.*

Finally, the November 2 FDA Letter challenges Cassava’s analysis of plasma-based (i.e., present in blood, not cerebrospinal fluid or “CSF”) biomarkers⁵ and its use to develop SavaDX, a putative blood test to detect Alzheimer’s disease. *Id.* at 18–21.

ii. The November 3 “Shambolic Charade” Presentation

The day after the Dot.Com Defendants filed their letter to the FDA, they also posted presentation slides on “cassavafraud.com.” (ECF 30-9). The second slide in the deck, titled *Cassava Sciences: A Shambolic Charade*, discloses that the Dot.Com Defendants “hold stock and options positions that may benefit from a decline in [Cassava’s] stock price.” (ECF 30-9 at 3). The presentation largely addresses the same points as the November 2 FDA letter, with more colorful graphics and spirited language. It adds, however, some references to individuals associated with Cassava and refers to them in less-than-favorable terms, calling them “The Cassava Gang: back together for one last heist” and “Old Friends and Conflicted Cronies,” and questions whether three alleged members of Cassava’s Scientific Advisory Board are “Asleep at the Switch, or Selling Out?” *Id.* at 9-11.

iii. The November 29 SavaDX Report

The SavaDX Report focuses on SavaDX, which Cassava claims to be a first-of-its-kind blood test that claims to detect Alzheimer’s disease before onset of any clinical symptoms of the disease. (ECF 30-12).⁶ Although discussed very briefly in the Neuroscientist Defendants’

⁵ The Dot.Com Defendants infer from published data – specifically the 2020 article in the *Journal of Prevention of Alzheimer’s Disease*, which was approved for publication six days after it was submitted (Neuroscientists’ R&R at 10; Wang et al., *PTI-125 Reduces Biomarkers of Alzheimer’s Disease in Patients*, J. PREV. ALZ. DIS. (2020)) – that the mechanism by which SavaDX may detect Alzheimer’s disease may be the ratio or quantity of native versus misfolded FLNA in the blood. (ECF 30-8 at 20). But, a comment from Dr. Burns suggests that SavaDX detects something in the blood – as yet undisclosed – that is an “indicator of altered FLNA in [the] brain.” *Id.* at 21.

⁶ The presentation ends at ECF 30-12 at 18. ECF pages 19–29 appear to be duplicates of earlier slides.

Citizen Petition in the Appendix (*see* ECF 30-5 at 33), this presentation by the Dot.Com Defendants focuses exclusively on the science behind SavaDX. It relies on Cassava’s publicly-reported data, some internet sleuthing, and a FOIA request to suggest that SavaDX is the ratio of two different sizes of FLNA fragments. (ECF 30-12 at 6–10). In the FOIA materials, one of Dr. Wang’s coauthors, Dr. Qiang Xu, included original, labeled Western blot images and results from a study that compared the relative presence of various-sized fragments of FLNA, which apparently contradicts the information presented in the Alzheimer’s Association International Conference (“AAIC”) poster,⁷ which was also the subject of the Neuroscientist Defendants’ inquiry (*see* ECF 30-5 at 33; *see* Neuroscientists’ R&R at n. 20).

iv. The December 14 Seeing Through the Blind Presentation

This presentation juxtaposes information obtained through FOIL and FOIA requests to City University of New York (“CUNY”)⁸ with public representations made by Cassava to assert that “both Cassava & Wang were NOT BLINDED during the open-label study.” (ECF 30-14 at 4–6) (emphasis in original).⁹ As discussed previously, in SEC filings and other public documents, Cassava has previously referred to the Wang lab at CUNY as an “outside” or “academic” lab. (*See, e.g.*, ECF 30-22, Exhibit 20 – Cassava Form 10-K, at 18). The Dot.Com Defendants also point

⁷ The presentation also points out that although SavaDX appears to be a ratio of two FLNA fragments, the AAIC poster only presents one band for each subject, from which it is impossible to calculate a ratio of two variables. The AAIC poster reflects only the 90kDa FLNA fragment, even though the raw data from Dr. Xu provides data for both the 90kDa and 280kDa FLNA fragments. The blots from Dr. Xu’s lab also look nothing like the blots presented in the AAIC poster. (ECF 30-12 at 12–15).

⁸ The CUNY FOIL material is linked at ECF 30-14 at 9. Also of concern, though not mentioned by the Dot.Com Defendants, the emails obtained via FOIL seem to indicate that the labels on some of the CSF sample tubes were not legible. *See, e.g.*, April 28, 2021, email to Dr. Xu: “because [of a] FedEx delivery problem, the plastic bag which contained all the tubes was broken and labels on some tubes were scratched by dry ice cubes. Would you please kindly send me the information of all samples in this package?” *Id.* at 12 in the linked FOIL material.

⁹ Again, ECF 30-14 appears to be two copies of the same slide deck. The presentation ends at ECF 30-14 at 10.

to an email obtained through a FOIA request, from a Wang lab member to Professor Xu, where the Wang lab member proposed labeling the CSF samples with the patients' initials.

(ECF 30-14 at 8).

III. ANALYSIS

A. Standard of Review

For the purpose of deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept all allegations in the complaint as true, and draw all reasonable inferences in the plaintiff's favor. *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985). If the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face," the complaint should not be dismissed. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant[s] [are] liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). For a claim to sufficiently "raise a right to relief above the speculative level," it must be grounded on factual allegations. *Twombly*, 550 U.S. at 555. A claim grounded on mere suspicion is not enough to meet this standard. *Id.* "[L]abels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557) (internal citation omitted, alteration in original).

Generally, “[w]hen considering a motion to dismiss, the Court’s review is confined to the pleadings themselves,” because “[t]o go beyond the allegations in the [c]omplaint would convert the Rule 12(b)(6) motion to dismiss into one for summary judgment pursuant to [Rule] 56.” *Thomas v. Westchester Cnty. Health Care Corp.*, 232 F. Supp. 2d 273, 275 (S.D.N.Y. Nov. 21, 2002) (citation omitted). However, “the Court’s consideration of documents attached to, or incorporated by reference in the [c]omplaint, and matters of which judicial notice may be taken, would not convert the motion to dismiss into one for summary judgment.” *Id.* (citations omitted); *Maroney v. Woodstream Corp.*, No. 19-CV-8294 (KMK), 2023 WL 6318226, at *1 (S.D.N.Y. Sept. 28, 2023). The Court can take judicial notice of public disclosures such as those filed with the SEC or FDA. *See, e.g., In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018) (taking judicial notice of three citizen petitions to the FDA).

B. The Defamation Claim Against the Dot.Com Defendants Should Be Dismissed

Under New York law, a complaint asserting defamation must plausibly allege five elements: “(1) a written defamatory statement of and concerning the plaintiff, (2) publication to a third party, (3) fault, (4) falsity of the defamatory statement, and (5) special damages or per se actionability.” *Palin v. N.Y. Times Co.*, 940 F.3d 804, 809 (2d Cir. 2019). When a defamation claim is brought by a public figure,¹⁰ the First Amendment independently requires a showing that the defendant acted with actual malice. *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 283 (1964).

¹⁰ Cassava does not deny that it is a public figure. (See ECF 81 at 5, 9: “Cassava does not and cannot deny that it is a public company that made public filings in pursuit of a drug it hopes to test on and sell to the public.”).

i. The Science-Based Statements are Not Defamatory

Most of the Dot.Com Defendants’ allegations are science-based and rely on Cassava’s own public statements and data, and other publicly available information obtained through FOIA and FOIL requests. From that publicly available information – exhaustively linked, referenced and analyzed – the Dot.Com Defendants raise the same questions about the integrity of the research underlying Cassava’s development of simufilam as were raised by the Neuroscientist Defendants. Framed one way, the Dot.Com Defendants summarize the publicly available data concerning simufilam and offer their opinion that the data, taken at face value, does not support Cassava’s claims about the efficacy or mechanism of simufilam as a treatment for Alzheimer’s disease, nor does the limited information suggest that SavaDX presents a viable way to detect Alzheimer’s disease before clinical symptoms appear. When framed that way, the Dot.Com Defendants’ scientific analysis fall squarely under *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), and is non-actionable. (*See also* analysis in Neuroscientists’ R&R at 18–20).

Cassava has claimed, however, that the reasoning in *ONY* does not apply if the alleged defamatory statements call into question the veracity of the underlying data. While it is true that the Dot.Com Defendants are more vocal (and hyperbolic) than the Neuroscientist Defendants in questioning the integrity of the underlying research, these statements are still not actionable under *Gross v. N.Y. Times Co.*, 82 N.Y.2d 146, 153–54 (N.Y. 1993), because these statements are “accompanied by a recitation of the facts on which [they are] based . . . and do[] not imply the existence of undisclosed underlying facts.” *Id.* (citing Justice Brennan’s dissent in *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 11–14 (1990), reasoning “a proffered hypothesis that

is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture.”). Here, as with the Neuroscientist Defendants, the Dot.Com Defendants’ statements draw the inference that the research on which Cassava relies to support clinical testing of simuflam in humans may be unreliable. (See Neuroscientists’ R&R at 20).

ii. Defendants’ Other Statements Are Not Defamatory

Cassava’s defamation claims rely principally on the Dot.Com Defendants’ challenges to the integrity of the research and published studies concerning simuflam and SavaDX, but the Dot.Com Defendants’ other statements are also not actionable. For example, Defendants’ statements about Cassava’s history, insiders, “shady players,” Scientific Advisory Board,¹¹ and one of its clinical investigators (ECF 30-9 at 7–11, 18) rely on and link to publicly available information, as the Dot.Com Defendants explain repeatedly. *See, e.g., id.* at 6. “[E]ven accusations of criminal behavior are not actionable if, understood in context, they are opinion rather than fact.” *Hayashi v. Ozawa*, No. 17-CV-2558 (AJN), 2019 WL 1409389, at *2–5 (S.D.N.Y. Mar. 28, 2019) (collecting cases) (noting that blog posts with a “hyperbolic and rhetorical tone” claiming a doctor of podiatry was not a doctor were protected statements of pure opinion). Moreover, as with *Ozawa*’s blog posts, context matters. The Dot.Com Defendants’ rhetorical and hyperbolic statements published on their websites named “cassavafraud.com” and “simuflimflam.com”¹² together with the Dot.Com Defendants’ disclosure of their short

¹¹ The slide concerning the Scientific Advisory Board members does not call them “shady” or refer to them as “insiders,” but rather asks whether they are “Asleep at the Switch, or Selling Out?” and adds a tweet in which one board member appears to deny affiliation with Cassava. (ECF 30-9 at 11).

¹² Moreover, to the extent Cassava takes issue with the publication and presence of these statements on the identified websites, “cassavafraud.com” and “simuflimflam.com,” the publication of non-actionable statements does not somehow make them defamatory. *See Goldman v. Barrett*, No. 15-CV-9223 (PGG), 2016 WL 5942529, at *5 (S.D.N.Y. Aug. 24, 2016) (publication of true statements on website called “quackwatch.com” did not imply

positions, (ECF 30-9 at 3), would be understood by an ordinary reader as pure opinion. *Hayashi*, 2019 WL 2409389, at *5.

The SAC also fails to plead facts supporting actual malice and causation for the same reasons I articulated in the Neuroscientist Defendants' R&R. (See Neuroscientists' R&R at n.28). The addition of a 365-page "appendix" listing over 1000 statements in the presentations as well as various Twitter/X posts¹³ does not save Cassava's claim. Read in context, the statements published on the websites and addressed in detail above are statements of opinion based on a full recitation of the facts (Cassava's own statements) on which they are based, and Cassava's repeated conclusory statements that these opinions are false does not make them actionable. (See Neuroscientists' R&R at 21).

Accordingly, because I find that the Dot.Com Defendants' statements are statements of opinion, specifically, inferences drawn from facts and data presented by Cassava, they are not actionable and I recommend that the Dot.Com Defendants' motion to dismiss be **GRANTED**.

C. The FAC Does Not Comply with Rule 8 and the Civil Conspiracy Claim is Abandoned

For the same reasons I articulated in the Neuroscientist Defendants' R&R, the civil conspiracy claim should be dismissed. (See Neuroscientists' R&R at n.30). The Dot.Com Defendants also "incorporate by reference" the Neuroscientist Defendants' argument that the FAC does not comply with Fed. R. Civ. P. 8(a), which I also addressed in my previous Report and

plaintiffs' involvement in healthcare fraud; declining to give a "strained or artificial construction" to find a defamatory implication).

¹³ See *Ganske v. Mensch*, 480 F. Supp. 3d 542, 552-53 (S.D.N.Y. Aug. 20, 2020) (finding tweets on Twitter/X were opinion and not actionable as defamation; Twitter/X is a forum "equally – if not more – informal and freewheeling" than many other internet fora, and statements published on Twitter/X were "generally informal and unedited" and given less credence by readers) (internal quotations omitted).

Recommendation as an alternative ground for dismissal. (*See* Neuroscientists' R&R at 22–23). In any event, Cassava has not addressed these reasons for dismissal in its opposition brief, and I see no reason to review or revisit that analysis.

IV. CONCLUSION

For the reasons above, I respectfully recommend that the Dot.com Defendants' motion be **GRANTED** in its entirety.

V. OBJECTIONS

In accordance with 28 U.S.C. §636(b)(1) and Fed. R. Civ. P. 72(b), the parties shall have fourteen (14) days (including weekends and holidays) from receipt of this Report to file written objections. *See also* FED. R. CIV. P. 6 (allowing three (3) additional days for service by mail). A party may respond to any objections within fourteen (14) days after being served. Such objections, and any responses to objections, shall be addressed to the Honorable Gregory H. Woods, United States District Judge. Any requests for an extension of time for filing objections must be directed to Judge Woods.

FAILURE TO FILE OBJECTIONS WITHIN FOURTEEN (14) DAYS WILL RESULT IN A WAIVER OF OBJECTIONS AND WILL PRECLUDE APPELLATE REVIEW. *See Thomas v. Arn*, 474 U.S. 140, 155 (1985); *IUE AFL-CIO Pension Fund v. Herrmann*, 9 F.3d 1049, 1054 (2d Cir. 1993); *Frank v. Johnson*, 968 F.2d 298, 300 (2d Cir. 1992); *Wesolek v. Canadair Ltd.*, 838 F.2d 55, 58 (2d Cir. 1988); *McCarthy v. Manson*, 714 F.2d 234, 237–38 (2d Cir. 1983).

Respectfully submitted,

Dated: January 5, 2024
New York, New York

/s/ Ona T. Wang

Ona T. Wang
United States Magistrate Judge